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| (51) International Patent Classification ⁵ : C11D 3/00, 3/20, A61K 31/565 | | A1 | (11) International Publication Number: WO 94/20598 (43) International Publication Date: 15 September 1994 (15.09.94) |
| (21) International Application Number: PCT/US94/02575 (22) International Filing Date: 10 March 1994 (10.03.94) (30) Priority Data: 08/031,153 12 March 1993 (12.03.93) US (71) Applicant: ALLERGAN, INC. [US/US]; 2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92713-9534 (US). (72) Inventor: WILLIS, Timothy, R.; 25222 Cinnamon Road, Lake Forest, CA 92630 (US). (74) Agents: VOET, Martin, A. et al.; Allergan, Inc., 2525 Dupont Drive, P.O. Box 19534, Irvine, CA 92713-9534 (US). | | | (81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> |
| (54) Title: EYE CARE PRODUCTS CONTAINING A PHEROMONE ADDITIVE AND METHOD OF USING THE SAME | | | |
| (57) Abstract Eye care products such as contact lenses, contact lens care solutions and eye care formulations which contain a pheromone additive such that the user of such eye care products experiences a good feeling and a sense of comfort, well-being and satisfaction when such products are used in the eye. | | | |

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**EYE CARE PRODUCTS CONTAINING A PHEROMONE ADDITIVE AND
METHOD OF USING THE SAME**

Field of the Invention

The present invention generally relates to eye care products containing a pheromone additive and more particularly relates to eye care products such as contact lenses, contact lens care solutions, and eye care formulations which contain a pheromone additive which enables the user of the eye care products to feel good and to achieve a sense of comfort, well-being and satisfaction.

Background of the Invention

The rapid development of various type of contact lenses during the past 20 years, i.e., hard contact lens, rigid gas permeable contact lens, silicon acrylate lens, soft contact lens made of either hydrophobic or hydrophilic materials has led to a variety of contact lens materials, contact lens care solutions, and other eye care products such as lid scrub solutions being developed for the consumer market. In the normal course of wearing and caring for contact lenses, the process of cleaning, disinfecting, and rinsing are necessary to ensure the ocular health of the contact lens wearer. In most instances, a different solution is used for each of the individual steps of cleaning, disinfecting, storing, and rinsing before the lenses can be inserted into the eyes. More recently, new lens care solutions have been developed that are capable of cleaning, disinfecting and rinsing contact lenses by a single solution.

Some contact lens wearers have allergic reaction to the presence of contact lenses in their eyes. As a consequence irritations in the eye or the eye lids have been observed. Some lid scrub solutions have been developed to alleviate such adverse allergic reactions caused by contact lenses. They can be used to wash and disinfect eye lids such that irritation or infection may be prevented.

Regardless of the fact that whether the adverse allergic reaction is caused by physiological or psychological reasons, some contact lens wearers found that having foreign objects in their eyes to be an uncomfortable and

2.

unpleasant experience. A statistical study shows that out of 100 people who stop using contact lenses, 71% are because of irritation and discomfort. It is therefore desirable to devise products that would alleviate such discomfort.

The present invention discloses a method of adding a pheromone
5 additive into a variety of eye care products such as contact lenses, contact lens care solutions, and eye care solutions such as a lid scrub solution so that the contact lens wearer would experience a good feeling and sensation of comfort, well being and satisfaction when such pheromone containing eye care product is placed in the eye.

10 One of such pheromones that works satisfactorily in the present invention is a androsterone which has a chemical formula of 3 alpha - hydroxy - 5 alpha androstane - 17 - one or $C_{19}H_{30}O_2$. It is believed that the pheromone acts in conjunction with the human vomeronasal organ, i.e., a chemosensory organ in the nasal cavity tied to the hypothalamus, to provide
15 the user with a feeling of comfort and well-being when the lens or solution having pheromone incorporated therein is placed in the eye.

Others have attempted to use pheromones in applications other than eye care products. For instance, U.S. Patent No. 4,456,587 to Keith discloses a pheromone delivery system in which emulsion polymers are used as carriers
20 of pheromone for slow release when the aqueous mixture is sprayed onto the leaves of cotton plants for the control of cotton tree insects.

U.S. Patent No. 4,923,119 to Yamamoto, et al. discloses a bag-like dispenser which contains a sex pheromone compound of insects used for sustained release of the pheromone compound at a uniform emission rate over
25 a long period of time. The bag-like dispenser body is formed of a specific polymeric laminated film having at least two or three layers in which one of the layers is a film of polyvinylidene chloride. Yamamoto, et al. compared their bag-like dispenser with other types of sustained release dispensers and claimed superiority over other types of dispensers such as microcapsules and
30 capillary tube-type dispensers.

U.S. Patent No. 4,959,353 to Brown, et al. discloses a method of promotion of corneal stroma wound healing with human epidermal growth factor prepared from recombinant DNA. Brown, et al.'s method for treating corneal stroma wounds is to promote regeneration of the affected tissue by
35 the incorporation of a polypeptide in ointment or cream to be used in the eye.

3.

Brown, et al. did not use an additive of pheromone and did not attempt to make the user of their ointment or cream to have a sense of good feeling.

U.S. Patent No. 4,855,127 to Abrutyn, et al. discloses solid compositions wherein a non-cosmetic functional material is entrapped in a lattice of a crosslinked polymer during in situ polymerization of the monomers forming the polymer lattice. It provides a method for converting solid or liquid products into solid, free-flowing forms by the entrapment of the functional materials in a hydrophobic polymer lattice. Abrutyn, et al. do not teach the use of pheromone in a hydrophilic polymer which is the base material used in most soft contact lenses. Furthermore, Abrutyn, et al. teach the use of very high percentage, i.e., 95% to 5% of pheromone in a completely different form of product, i.e., free-flowing powders. The powder is used in products of molded wax or oil based sticks of the type typically used for antiperspirants, deodorants, and insect repellents, etc.

U.S. Patent No. 4,664,847 to Williams discloses a hydrophilic monomer such as hydroxypropyl methacrylate and a lipophilic monomer such as lauryl methacrylate copolymerized together in the presence of a fragrance or other volatile active ingredient. The resulting polymer made by Williams contains entrapped active ingredient which tends not to exude from the polymer during storage yet is gradually released when the polymer is exposed to the atmosphere such as in the case of an air-freshener. The purpose of Williams' invention was to replace a portion of the hydrophilic monomer with a particular type of lipophilic polymer such that the undesirable exudation process which normally results in a greasy or wet surface can be avoided.

U.S. Patent No. 4,310,397 to Kaetsu, et al. discloses polymer compositions containing a physiologically active substance. The polymer is polymerized by the irradiation of light or an ionizing source while maintaining the system in an anhydrous and airless condition. The Kaetsu, et al. method would not work in a soft contact lens composition made with hydrophilic polymers since the Kaetsu, et al.'s method only works in an anhydrous condition.

It is therefore an object of the present invention to overcome the various drawbacks associated with the use of prior art methods.

It is another object of the present invention to provide eye care products in the form of contact lenses incorporating a pheromone in the contact lens

4.

polymer such that the wearer of the contact lenses experiences a feeling of comfort and well-being.

It is yet another object of the present invention to provide eye care products in the form of a contact lens care solution that contains a
5 pheromone such that the user of contact lenses cleaned by such a solution would have a good feeling and a sense of comfort and satisfaction.

It is a further object of the present invention to provide eye care products in the form of an eye care solution such as a lid scrub solution containing a pheromone such that the user of such solution would feel good
10 and would have a sense of comfort, satisfaction, and well-being.

It is another further object of the present invention to provide a method of using eye care products that contains a pheromone such that the user would feel good and have a sense of comfort, well-being, and satisfaction.

It is yet another further object of the present invention to provide a
15 method of incorporating a pheromone into eye care products such as contact lenses, contact lens treatment solutions, and eye care solutions such as lid scrub so that a sustained release of the pheromone occurs to render the user a sense of good feeling, comfort, satisfaction, and well-being.

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Summary of Invention

In an effort to develop eye care products that are more user-friendly, less irritable to the eyes and thus more easily accepted by consumers, the inventor has accidentally discovered that by the incorporation of a pheromone in eye care products a sense of good feeling, well being, and comfort can be experienced by the user of the products.

In accordance with a first embodiment of the present invention, a pheromone can be used as an additional ingredient into the polymerization process of a hydrophilic contact lens such that the pheromone is incorporated in situ with the hydrophilic polymer structure. The pheromone is volatile in nature and can be controlled to release through a process of sustained slow release. This enables the user of the contact lens to have a comfortable and good feeling every time the lens is inserted into the eye. It is believed that the pheromone is in the water portion of the lens matrix with some pheromone bound to the matrix polymer. Pheromone slow releases by a diffusion process over a predetermined period of time depending upon how it is bound to the matrix polymer.

The amount of the pheromone incorporated into the polymerization process is relatively small compared to the total content of the monomer. As a result, the pheromone does not interfere with the polymerization process. A suitable pheromones for the present invention is androsterone. However, any other pheromone capable of producing a sense of good feeling and well-being in the user may also be used.

In a second embodiment of the present invention, a pheromone is incorporated into contact lens care solutions such as those used for cleaning, disinfecting, storing, rinsing, and neutralizing. A small amount of pheromone is added to the solution such that every time the contact lens user uses the solution to treat the lenses and then inserts the lenses into the eyes, the user achieves a sense of comfort, good feeling, and satisfaction. When a suitable amount of pheromone is added to the solution, it is believed that this sense of good feeling and well-being can last for extended period of time.

In a third embodiment of the present invention, a pheromone is added to an eye care solution such as a lid scrub formulation. Each time the patient uses the lid scrub formulation to treat the eye lids, a sense of comfort and good feeling is experienced by the user.

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The present invention is also directed to a method of using a pheromone in eye care products such as contact lenses, contact lens care solutions, and other eye care formulations. The method comprises the step of adding a pheromone into a polymerization process for contact lenses such that the

5 pheromone is incorporated into the polymer in-situ or adding a pheromone to contact lens care solutions or eye care formulations by a small amount, i.e., from about 0.0001% to about 15% (w/v). The contact lenses and the eye care formulations can then be used in the eye, or contact lenses can be

10 treated with contact lens care solutions containing pheromone for a suitable length of time before they are inserted into the eyes.

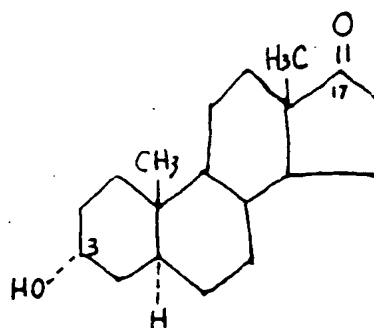
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Detailed Description of the Embodiments

The present invention is directed to new and improved eye care products that incorporates a pheromone as an additive or as a base solution. The present invention is also directed to a method of using such eye care products. The pheromone, specifically androsterone, acts in conjunction with the vomeronasal organ, i.e., a chemosensory organ in the nasal cavity connected to the hypothalamus, provides the user with a sense of good feeling, comfort and satisfaction when the lenses or the eye care formulations touch the eyes.

Androsterone may exist in several chemical forms such as 3 α -hydroxy-5 α -androstane-17-one; cis-androsterone; 3 α -hydroxy-17-androstanone; androstan-3(α)-ol-17-one; 3(α)-hydroxyetioallocholan-17-one; and 3-epihydroxyetioallocholan-17-one. It has a formula of C₁₉H₃₀O₂ and a molecular weight of 290.43. It is isolated from male urine after removal of the phenolic estrogen fraction. It is disclosed in U.S. Patent No. 2,232,735 to Schering which is incorporated hereby by reference.

Androsterone can be shown empirically as



Crystals of androsterone can be obtained from acetone-ether. It has a melting point of 185-185.5° C. and it sublimes in high vacuum.

In the first embodiment of the present invention, a pheromone is added to the contact lens polymer by the incorporation of a pheromone in an in-situ polymerization process. This in-situ polymerization process can be readily employed with all kinds of materials for contact lenses such as that for conventional hard, soft, gas permeable and silicon lenses. However, it is

8.

especially suitable for soft contact lenses of hydrophilic base such as those commonly referred to as hydrogel lenses prepared by monomers such as hydroxyethyl methacrylate, hydroxyethyl methyl methacrylate, vinylpyrrolidone, glyceromethacrylate, methacrylate esters and the like.

5 In the polymerization process, a suitable amount of androsterone, i.e., between about 0.0001% to about 15% by weight, is blended with the polymerization monomers before the monomers are poured into a mold and cured by irradiation with electron beams or radioactive rays. Producing the lens by polymerization and shaping is well known in the art. Any of the well
10 known techniques may be used. One such method teaching the manufacture of soft contact lenses not containing androsterone is described in U.S.P.N. 4,966,924 to Hyon, et al. which is incorporated hereby by reference.

Into a polyvinyl alcohol (PVA) monomer (degree of saponification of 99.5% by mole, viscosity-average degree of polymerization of 1,700),
15 androsterone and a mixture of solvents containing 20% by weight of water and 80% by weight of dimethyl sulfoxide are added so as to obtain a solution containing 10% by weight of PVA and 1% by weight of androsterone. After heating in an autoclave at 100° C. for 2 hours and then cooling to 50 ≈ 80° C., the solution is poured into a mold and allowed to stand for 1 hour in a
20 freezer kept at -20° C. The resulting PVA gel containing 1% by weight androsterone is taken out of the mold and organic solvents in the gel were exchanged with water by immersing the gel in plenty of water (at 40 ≈ 60° C.) to produce a PVA soft contact lens.

In the second embodiment of the present invention, a pheromone is
25 incorporated into contact lens care solutions. In Examples 1 and 2, a pheromone of androsterone is added to a lens care solution for contact lens disinfection containing sodium chlorite and polyvinyl pyrrolidone (PVP). The amount of androsterone used is 0.3% and 0.6% (w/v), respectively.

It is believed that any amount in between a minimum functionally active
30 amount (or therapeutically effective amount) and a maximum functionally active amount (or therapeutically effective amount) that will give good feeling when drops are put in eyes can be utilized in the present invention. A preferred amount of pheromone to be used is between about 0.0001% to 15% (w/v). A more preferred amount of pheromone to be used is between
35 about 0.01% to 5% (w/v).

9.

Example 1:

A pheromone of androsterone is blended with contact lens disinfecting solutions containing sodium chlorite and polyvinyl pyrrolidone.

| | <u>Ingredients</u> | <u>% (w/v)</u> |
|----|-----------------------------|----------------|
| 5 | Sodium chloride | 0.62 |
| | Boric acid | 0.473 |
| | Sodium borate decahydrate | 0.090 |
| | Sodium chlorite | 0.0214 |
| | PVP, Kollidon® K-30 or K-25 | 0.50 |
| 10 | Androsterone | 0.3 |

Example 2:

Androsterone is blended with contact lens disinfecting solutions containing sodium chlorite and polyvinyl pyrrolidone.

| | <u>Ingredients</u> | <u>% (w/v)</u> |
|----|---------------------|----------------|
| 15 | Sodium chloride | 0.62 |
| | Boric acid | 0.473 |
| | Sodium borate | 0.090 |
| | Sodium chlorite | 0.0223 |
| | PVP, Kollidon® K-30 | 0.50 |
| 20 | Androsterone | 0.60 |

PVP is used in ophthalmic preparations in order to increase the viscosity of the solution. In some eye drops PVP is used to prolong the therapeutic action of substances such as pilocarpine and to promote the bioavailability of drugs. PVP is also used in solutions for contact lenses. Various grades of PVP are commercially available from BASF Aktiengesellschaft of Ludwigshafen, Germany under the name of Kollidon®. For example, the following grades of Kollidon® are soluble forms of PVP: K-12 PF (molecular weight \approx 2,900); K-17 PF (molecular weight \approx 9,000); K-25 (molecular weight \approx 29,000); K-30 (molecular weight \approx 45,000); and K-90 (molecular weight \approx 1,100,000).

In examples 3 and 4, a pheromone of androsterone is added to a lens care solution for contact lens cleaning and disinfecting containing a non-ionic surfactant and a triquaternary phosphate ester. The amount of androsterone used in Examples 3 and 4 was 0.8% and 1.6% (w/v), respectively. However,

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it is believed that any other suitable amount in between 0.0001% to 15% (w/v) may also be used to achieve the same desirable result.

Example 3:

5 A cleaning, disinfecting, and rinsing solution for contact lenses containing 30 androsterone is prepared with the following composition:

| | <u>Ingredients</u> | <u>% (w/v)</u> |
|----|-------------------------|----------------|
| | Boric acid | 0.80 |
| | Sodium borate | 0.020 |
| 10 | Sodium chloride | 0.30 |
| | EDTA | 0.05 |
| | Pluronic® P85 | 0.50 |
| | Phospholipid® PTC | 0.03 |
| | Hydroxy Ethyl Cellulose | 0.50 |
| 15 | Androsterone | 0.80 |

Example 4:

20 A new and improved cleaning, disinfecting, and rinsing solution for contact lenses containing androsterone is prepared by the following composition.

| | <u>Ingredients</u> | <u>% (w/v)</u> |
|----|-------------------------|----------------|
| | Boric Acid | 0.80 |
| | Sodium borate | 0.20 |
| | Sodium chloride | 0.30 |
| 25 | EDTA | 0.10 |
| | Pluronic® P85 | 0.50 |
| | Phospholipid® PTC | 0.03 |
| | Hydroxy Ethyl Cellulose | 0.50 |
| 30 | Androsterone | 1.60 |

35 A suitable family of surfactants for use in Examples 3 and 4 can be obtained commercially from the BASF Corporation under the trade name of Pluronic® surfactants. This family of block copolymers can be generally described as polyoxyethylene/polyoxypropylene condensation polymers terminated in primary hydroxyl groups.

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Phospholipid® PTC is a microbiocidal agent of a triquaternary phosphate ester of cocoamidopropyl PG dimonium chloride phosphate. It is commercially available from Mona Industries.

5 In the third embodiment of the present invention, a pheromone is added to a variety of eye care products. An illustrative example is shown below in which androsterone is added to a lid scrub formulation. A suitable percentage of androsterone to be used is between about 0.0001% to about 15% (w/v).

The following formulations are typical lid scrub compositions.

10 Example 5:

| | <u>Ingredients</u> | <u>% (w/v)</u> |
|----|--------------------------|----------------|
| | Miranol® MS-2 | 7 to 10 |
| | PEG- 15 Tallow Polyamine | 0.1 - 0.5 |
| | Sodium Chloride | 0.6 - 0.9 |
| 15 | Quaternium-15 | 0.1 - 0.5 |
| | Disodium EDTA | 0.1 |
| | Androsterone | 0.30 |

20 Example 6:

| | <u>Ingredients</u> | <u>% (w/v)</u> |
|----|-------------------------|----------------|
| | Miranol® MS-2 | 7 to 10 |
| | PEG-15 Tallow Polyamine | 0.1 - 0.5 |
| | Sodium Chloride | 0.6 - 0.9 |
| | Quaternium-15 | 0.1 - 0.5 |
| 25 | Disodium EDTA | 0.1 |
| | Androsterone | 0.60 |

Example 5 and Example 6 each shows a non-irritating liquid cleansing composition for cleaning eye lids. Either composition can be used to alleviate
30 or prevent the symptoms of Blepharitis, a common chronic inflammation of the eye lids characterized by a scaly crust on the lid margins. This condition is frequently caused by a bacteria infection, an allergic reaction, or associated with seborrhea of the face and scalp. To treat Blepharitis, the eye lids must be cleaned on a regular basis to prevent the build up of oil, debris and dust
35 which foster a bacteria infection.

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The lid scrub formulations disclosed in Examples 5 and 6 contain a major ingredient of a mixture of surfactants marketed by Miranol Chemical Company (Dayton, N.J.) under the trade name of MS-2. This mixture of surfactants includes PEG-80, sorbitanlaurate, sodium trideceth sulphate, PEG-150 distearate, cocamidopropylhydroxy sultaine, lauroamphocarboxy glycinate, and sodium laureth-13 carboxylate. The compositions also include sodium chloride, an emollient and surfactant agent of PEG-15 tallow polyamine, a micro biological preservative which may be Quaternium-15, or benzyl alcohol, and optionally, a chelating agent such as sodium EDTA. Quaternium-15 is well known for its microbiological preservative property and has been used as an ingredient in skin care compositions. It is N-(3-chloroallyl) hexamminium chloride, a quaternary ammonium salt marketed by Dow Chemical Company under the trade name of Dowacil® 200. The lid scrub composition not containing androsterone is disclosed in U.S.P.N. 4,904,698 which is incorporated hereby by reference.

The applications of the lid scrub composition are greatly enhanced by the addition of a pheromone of androsterone at either 0.3% (w/v) or 0.6% (w/v). Eye lid cleaning is normally regarded as a tedious and unpleasant task for someone to rid of Blepharitis problem since washing the eye lids would inevitably involve touching or rubbing against the eye balls. With the addition of androsterone, the patient feels good every time the eye lids are cleaned by the novel lid scrub composition. The good feeling can last for a period of time during which the patient feels relaxed and satisfied. This novel invention of adding pheromone to lid scrub compositions therefore greatly ease the burden on the patient and turning an unpleasant task into a pleasant one.

It should be appreciated that the compositions disclosed in Examples 1 through 6 are merely given as illustrative examples, any suitable pheromone can be added to any other eye care product. It is worth noting that since androsterone has limited solubility in water, it may be desirable to add a suspending agent or dispersant into the aqueous solution to facilitate the dispersion of androsterone in the eye care or lens care product. Androsterone may also be ground to very small particle size to achieve better dispersion in water.

The present invention may also include applications in nose spray or spray useful in dental applications. Pheromone may be added to a nose spray

13.

or a spray or solution used in dental applications to make the patient feel good.

While this invention has been described in an illustrative manner, it should be understood that the terminology used is intended to be in the
5 nature of words of description rather than of limitation.

Furthermore, while the invention has been described in terms of three preferred embodiments thereof, it is to be appreciated that those skilled in the art will readily apply these teachings to other possible variations of the invention.

10 The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

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What is claimed is

1. A novel eye care product containing between about 0.0001% to about 15% (w/v) of a pheromone .
2. An eye care product according to claim 1 wherein said product is a contact lens.
3. An eye care product according to claim 1 wherein said product is a contact lens care product.
4. An eye care product according to claim 1 wherein said product is an eye care formulation.
5. A novel eye care product containing between about 0.0001% to about 15% (w/v) of androsterone.
6. An eye care product according to claim 3 wherein said contact lens care product is a contact lens rinsing solution.
7. An eye care product according to claim 3 wherein said contact lens care product is a contact lens neutralizing solution.
8. An eye care product according to claim 3 wherein said contact lens care product is a contact lens cleaning solution.
9. An eye care product according to claim 3 wherein said contact lens care product is a contact lens disinfecting solution.
10. An eye care product according to claim 1 wherein said eye care product is a lubricating/wetting product for contact lens wearer and dry eye.
11. An eye care product according to claim 4 wherein said eye care product is an eye lid cleaning solution.

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12. A method of using a pheromone containing eye care product comprising the steps of adding said pheromone to said eye care product and subsequently contacting the eye with said product.

13. A method according to claim 12 wherein said eye care product is a contact lens.

14. A method according to claim 12 wherein said eye care product is a contact lens care solution.

15. A method according to claim 12 wherein said eye care product is an eye care product.

16. A method according to claim 14 wherein said contact lens care product is a contact lens rinsing solution.

17. A method according to claim 14 wherein said contact lens care product is a contact lens neutralizing solution.

18. A method according to claim 14 wherein said contact lens care product is a contact lens cleaning solution.

19. A method according to claim 14 wherein said contact lens care product is a contact lens disinfecting solution.

20. A method according to claim 12 wherein said eye care product is a lubricating/wetting product for contact lens wearer and dry eye.

21. A method according to claim 15 wherein said eye care product is an eye lid cleaning solution.

22. A method of providing an eye care product user with a good feeling when the eye care product user uses the eye care product, the method comprising adding to the eye care product a pheromone.

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23. A medical product containing between about 0.0001% to about 15% (w/v) of a pheromone.

24. A medical product according to claim 23 wherein said product is a nose spray.

25. A medical product according to claim 23 wherein said product is a spray or solution useful in dental applications.

INTERNATIONAL SEARCH REPORT

Inte...nal Application No
PCT/US 94/02575A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 C11D3/00 C11D3/20 A61K31/565

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 C11D A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| P,A | WO,A,93 20823 (SCHEPEN'S EYE RESEARCH INSTITUTE INC.) 28 October 1993 see page 5, line 5 - line 27 see page 32; claims ----- | 1 |

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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